PUBLIC NOTICE
Initiation of Risk Assessments for Chemicals in Drinking Water
June 2006

A. Requirements

The Calderon-Sher California Safe Drinking Water Act of 1996 requires the Office of Environmental Health Hazard Assessment (OEHHA) to post notices on its Web site of water contaminants for which it is initiating work, pursuant to development of a public health goal (PHG) for the chemical in drinking water. The law also describes the intent and general context of the PHGs. PHGs are concentrations of chemicals in drinking water that are not anticipated to produce adverse health effects following long-term exposures. These goals are non-regulatory in nature but are to be used as the health basis to update the state's primary drinking water standards (maximum contaminant levels, or MCLs) established by the California Department of Health Services (DHS) for chemicals subject to regulation.

The act requires PHGs to be developed for the approximately 87 chemicals for which state MCLs are presently available, and review and update of the risk assessments at least every five years. Other chemicals may be added to the list by legislative or interdepartmental request. Opportunities for public comment and peer review are provided.

B. Implementation

OEHHA has published 80 PHGs as of March 2006, although one of these evaluations, that for total chromium, has been rescinded. Two MCLs, for gross alpha and gross beta radionuclides, represent screening levels for contaminants rather than specific regulatory standards; for these, OEHHA has provided risk assessments and guidance memoranda. The technical support documents for these chemicals are posted on the OEHHA Web site at www.oehha.ca.gov.

PHGs for all the other chemicals that have state MCLs are currently in preparation. Drafts for public comment on five of these chemicals are posted on the OEHHA Web site. PHGs for the remaining chemicals with existing MCLs should be released for public review this year. A 45-day public comment period will be provided after posting, followed by a public workshop. The overall process includes an opportunity for scientific peer review arranged through the University of California, allotting time for revisions, further public comment, and preparing responses to comments.

The PHG re-evaluation has been completed for thallium, inorganic mercury, lindane, and 1,2-dichloroethane. OEHHA concluded that no new information was available on these chemicals that would require significant changes to the PHG document. Memoranda to

this effect are available at http://www.oehha.ca.gov/water/reports/index.html. The re-reviews of several other chemicals that were announced in 2004 or 2005 are in progress.

Evaluation is now being initiated for several other chemicals for which PHGs were developed earlier, which will now be re-reviewed as part of the ongoing PHG update process. Comments are requested on each of these chemicals.

C. PHGs to be released for public review:

Draft documents for the following chemicals are nearing completion, and are planned for release for public review and comment:

- Chlorite
- 2,4-Dichlorophenoxyacetic acid (2,4-D)
- Molinate
- Selenium
- Styrene
- Trihalomethanes

Comments were received during and after the first posting for public comment on the following chemicals, and the PHG documents are being prepared for a second posting for public comment:

- Cadmium
- Copper
- Dioxin
- Glyphosate
- Nitrosodimethylamine
- Polychlorinated biphenyls (PCBs)

D. Initiation of risk assessments

Risk assessment is being initiated for the following list of chemicals:

- Alachlor
- Atrazine and simazine
- Chlordane
- 1,3-Dichloropropene (Telone)
- Fluoride
- Lead
- Nitrate/nitrite

These risk assessments are updates of assessments prepared in the first years of our program. The chemicals have been prioritized on the basis of availability of new data and significance as drinking water contaminants. A brief description of the chemicals is provided below. This announcement solicits the submission of pertinent information on

the contaminants that could assist our office in preparing or updating the risk assessment and deriving a PHG.

Information submitted to OEHHA in response to this request should not be proprietary in nature, because all information submitted is a matter of public record. Information should be submitted by **August 31, 2006** to:

Thomas Parker
PHG Project
Pesticide and Environmental Toxicology Section
Office of Environmental Health Hazard Assessment
P.O. Box 4010
Sacramento, California 95812-4010

All data submitted will be considered in the development of the PHG for these chemicals. If substantive revisions to the original PHG documents are required, the draft documents will be available for discussion in a public workshop and public comment will be solicited as described above in Section B. The final risk assessments will be utilized by DHS in potential revisions to the MCLs for the chemical in drinking water, as described in more detail on the DHS Web site at http://www.dhs.ca.gov/ps/ddwem/chemicals/chemindex.htm.

E. Descriptions of chemicals or substances for initiation of review:

Alachlor

The Public Health Goal (PHG) of 4 ppb for alachlor, 2-chloro-N-(2,6-diethylphenyl)-N-(methoxymethyl)acetamide, was developed by OEHHA and published in December, 1997. Alachlor is a broad-range herbicide used to contain broadleaf weeds and annual grasses. Alachlor has been associated with various toxic effects in experimental animals including liver toxicity and corneal changes. However, the increased occurrence of nasal turbinate tumors in experimental animals serves as the basis for its risk assessment. Using a nonlinear approach in determining the risk, OEHHA identified a NOAEL of 0.5 mg/kg-day as the highest dose at which no increases in nasal turbinate tumors were noted. The U.S. EPA's MCL of 2 ppb, developed in 1991, is still in effect and is based on a different study than the one used for PHG development. The California MCL is also 2 ppb, established in September, 1994. Alachlor has not been listed as detected in public water supplies over the last few years in the DHS summaries of chemicals detected in drinking water sources.

In the survey of the literature, many additional studies relating to the effects of alachlor have been found since the publication of the PHG in 1997. The new toxicity information appears likely to have significant impact on the existing toxicology and risk assessment sections of the PHG. The studies presented below represent a selection of the available data, which will require detailed review to determine whether it will result in revision of the PHG value. The relatively low annual use of alachlor in California (under 30,000

pounds of active ingredient per year over the last few years) represents a mitigating factor in potential concern about human exposure.

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Atrazine and Simazine

The PHG of 0.15 ppb for atrazine was developed by OEHHA and published in December 1999, while the PHG of 4 ppb for simazine was published in 2001. These chemicals are selective pre- and post-emergent herbicides widely used on many food crops. They are members of the important family of triazine herbicides, which are currently being reevaluated together to ensure consistency in the risk assessments for these similar chemicals.

Atrazine has a variety of effects including carcinogenicity in experimental animals. The PHG is based on an increase in mammary tumors in female rats in which the

carcinogenic slope factor was estimated at 0.23 $(mg/kg\text{-}day)^{-1}$. Although atrazine was associated with an increase in mammary tumors in male rats as well, it failed to produce increased tumors in the mouse study. The PHG is lower than U.S. EPA's MCL of 3 ppb developed in 1991. U.S. EPA chose not to derive a carcinogenicity potency factor, but instead used a noncarcinogenic effect and an additional uncertainty factor for possible carcinogenicity. The California MCL is also 3 ppb, established in September 1994.

The PHG for simazine is based on a no-observed adverse-effect level (NOAEL) of 0.5 mg/kg for reduced body weight observed in female Sprague-Dawley rats administered simazine in the diet at 0, 10, 100 or 1,000 ppm for 24 months. There is suggestive evidence that simazine is a carcinogen, based on a finding of mammary gland carcinogenicity and ovarian hyperplasia and adenoma in a single study in female Sprague-Dawley rats, plus the data on mammary carcinogenesis for related triazine herbicides. Simazine is a weak mutagen. Reduced body weight is a consistent finding following simazine exposure of several species. The PHG calculation incorporates an adult body weight of 70 kg, drinking water consumption of 2 L/day, a 20 percent relative source contribution, and a combined uncertainty adjustment factor of 1000 (10-fold for inter-species variation, 10-fold for intra-species variation, and 10-fold to account for uncertainties associated with simazine carcinogenicity). The maximum contaminant level (MCL) for simazine in drinking water for both California and the U.S. Environmental Protection Agency (U.S. EPA) is 4 ppb.

Many additional studies relating to the effects of the triazine herbicides have appeared since publication of the atrazine PHG in 1999. In the PHG for simazine, published in 2001, similar mammary cancer evidence was interpreted as a rat-specific endocrine effect not applicable to humans. U.S. EPA has reexamined the basis for the carcinogenicity of atrazine, and concluded in their April, 2002 reregistration eligibility document that atrazine should not be considered a human carcinogen. The California Department of Pesticide Regulation Risk Characterization Document concurred with this interpretation. The U.S. EPA has also concluded that the triazine pesticides share a common mechanism of toxicity. The new data, including new information on the endocrine disruption potential of both herbicides, should be incorporated into the revised PHG document.

Since these herbicides are heavily used and leach into groundwater, there is a human exposure concern. The triazine herbicides and their metabolites were the most frequently detected pesticides in California's Well Inventory Database in 1985-2003.

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Chlordane

The Public Health Goal (PHG) of 3 x 10^{-5} ppb for chlordane was developed by OEHHA and published in December 1997. Chlordane is a broad-spectrum insecticide used to control termites and pests on field crops. All uses have been banned in the United States. Because chlordane is a very stable chemical, it is anticipated to persist in the environment for some time, making it still available for human exposure. Animal studies in rats and mice provide sufficient evidence for the carcinogenicity of chlordane, based on incidences of liver cancer including carcinomas, hemangiomas, and adenomas. A cancer slope factor of 1.3 $(mg/kg\text{-}day)^{-1}$ was used to derive the PHG. A noncancer safe dose was also calculated, but it was not used to determine the PHG, because the cancer dose provided a greater level of exposure protection. The U.S. EPA MCL for chlordane is 0.002 ppb (established in 1991), and the California MCL is 0.001 (established in 1990). California DHS has not proposed to revise the MCL to bring it closer to the PHG, and chlordane has not recently been detected in California drinking water in analyses reported by DHS (1984-2001).

Several potentially relevant new studies were identified. Also, U.S. EPA published a Toxicological Review of chlordane in 1998 and the International Agency for Research on Cancer (IARC) issued a monograph in 2001 reviewing the carcinogenicity of chlordane and similar compounds. Both of these reviews reaffirm the carcinogenicity of chlordane. However, no new toxicity studies were located which appear likely to result in a change of the PHG value for chlordane. Since the development of the PHG, the Integrated Risk Assessment Section of OEHHA has reassessed chlordane to develop a child-specific noncancer safe dose. Based on their review of chlordane toxicity, they have proposed a children's RfD that differs from the noncancer safe dose developed for the PHG document, which must be acknowledged in this review.

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1,3-Dichloropropene (Telone)

The Public Health Goals (PHGs) of 0.2 ppb for 1,3-dichloropropene was developed by OEHHA and published in December 1999. 1,3-Dichloropropene, a chlorinated hydrocarbon, is used as a soil fumigant, primarily to control nematodes. 1,3-Dichloropropene is very toxic and causes a variety of effects including severe irritation of the proximate exposed tissues, the skin and the respiratory tract. Because of its volatility, 1,3-dichloropropene has been an air contaminant issue. The principal human health concern from 1,3-dichloropropene is its potential carcinogenicity. There is sufficient evidence from experimental studies that 1,3-dichloropropene is carcinogenic. The PHG is based on a potency factor of 0.091 $(mg/kg\text{-}day)^{-1}$ for 1,3-dichloropropene. The California MCL is 0.5 ppb, established in 1988. U.S. EPA has judged 1,3-dichloropropene to be a probable human carcinogen (B2), but has not developed an MCL for this chemical; the proposed MCLG is zero. 1,3-Dichloropropene was not detected in public drinking water supplies analyses reported by DHS from 1984-01.

Many additional studies relating to the effects of 1,3-dichloropropene have appeared in the literature since the publication of the PHG 1n 1999, and the articles below represent only a subset of them. The new data may not lead to a revision of the PHG value because none of the new studies appear to suggest a more conservative estimate of the potency

value. However, the noncarcinogenic risk value derived in the PHG document could change as a result of a review of the new information. There is a significant ongoing potential for human exposure, primarily through the air pathway.

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Fluoride

The Public Health Goal (PHG) of 1 ppm for fluoride was developed by OEHHA and published in December 1997. Fluoride is added to drinking water for the prevention of dental caries. Fluoride salts also occur in geological formations, and therefore are found naturally in some drinking water sources. The PHG was based on a no-observed-adverse-effect-level (NOAEL) of 1 mg/L for dental fluorosis in children. The U.S. EPA has two MCLs for fluoride. The primary MCL is 4 ppm with a secondary MCL of 2 ppm; both were developed in 1986. The California MCL is also 2 ppm, established in April 1998.

Addition of fluoride to drinking water continues to be controversial, with many reports on the low-level effects. New toxicity data was located for the reproductive and testicular effects of fluoride. New epidemiological studies on the relationship between fluoride and cancer in Scandinavian and Japanese populations have been published, as well as a new study on bone cancer in young American males. In addition, a major review on fluoride toxicity by a committee of the National Academy of Sciences has just been published, which recommends that the U.S. EPA MCL of 4 ppm be lowered. However, this review takes no position on exposure to fluoride at the 1 ppm level commonly used for fluoridation.

Our review has not identified data that appear likely to result in substantive changes to the risk assessment methodology or the conclusions reached in the 1997 PHG report for fluoride, although substantial updating of the animal toxicology and human cancer sections appear to be needed.

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Lead

The Public Health Goal (PHG) of 2 ppb for lead was developed by OEHHA and published in December 1997. Lead is a metallic element used primarily in piping, paints, cable coverings, bullets, and radiation shielding material. It is a widespread contaminant

in the human environment and occurs in drinking water as a consequence of leaching from plumbing containing lead. Lead was reported in 1,481/11,471 drinking water analyses in the DHS survey results for 1984-2001.

Lead has multiple toxic effects on the human body. Decreased intelligence in children and increased blood pressure in adults are among the more serious non-carcinogenic effects. Lead is also a carcinogen in animals and is a probable carcinogen in humans (IARC and U.S. EPA). Based on studies correlating blood lead levels with decreased IQ in children, a daily oral intake from water of 28.6 μg/day was used to derive the PHG. A NOAEL was not found for this effect. A health-protective concentration for cancer effects of 6 ppb was also calculated, but it was not used to determine the PHG as the non-cancer level provided a greater exposure protection. Both the U.S. EPA and California have a regulatory Action Level of 15 ppb (now called Notification Level in California). If lead at or above the Notification Level is found in a system, measured at the tap, more monitoring, investigation of sources, and a public education program is instituted. The current regulatory level was established in 1991 by the U.S. EPA and in 1995 in California.

A plethora of research articles has been published since the PHG was published in 1997. The focus of the current literature review was on new data on effects of lead on human development, effects in adults, mechanism of action of lead, and its potential carcinogenicity. Because of the new human epidemiological studies regarding lead exposure and effects, as well as new data on the mechanism of action of lead, substantial updating of the PHG document is warranted. Changes may be required in the PHG calculation.

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Nitrate/nitrite

The Public Health Goal (PHG) of 10 ppm for nitrate-nitrogen (equivalent to 45 ppm nitrate), 1 ppm for nitrite-nitrogen, and 10 ppm for joint nitrate and nitrite (expressed as nitrogen) was developed by OEHHA and published in December 1997. Exposure to nitrates and nitrites results primarily from dietary ingestion (especially vegetables and cured meats) with an average adult daily intake estimate of 40 to 100 mg for nitrate and 0.3 to 2.6 mg for nitrite. However, nitrate is also commonly found in drinking water (reported by DHS in 9,992/13,914 samples in 1984-2001), and nitrite is occasionally found (70/10,940 samples). Nitrate is the second most-common chemical in number of measurements exceeding the MCL in California municipal water supplies.

The PHG for nitrate was based on protection of infants from methemoglobinemia, the principal toxic effect observed in humans exposed to nitrate or nitrite, derived from epidemiological studies. The value for nitrite was based on extrapolation from the value for nitrate. The PHG values are identical to MCLs adopted by the California Department of Health Services in 1994 and to those promulgated by U.S. EPA in 1991.

A considerable amount of new toxicity information was located on nitrate and nitrite, including data on mechanism(s) of action, thyroid effects, testicular effects, and interaction with other environmental chemicals. In addition, new epidemiological studies looking at the relationship between nitrate/nitrite and cancer in several populations have been published, which will require careful review.

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